Additional Information

Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW, Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: March 22, 2000.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 00–7520 Filed 3–27–00; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 79F–0401]

Thomas J. Lipton, Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 0A3481) proposing that the food additive regulations be amended to provide for the safe use of methylene chloride as a solvent for decaffeinating tea.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3110.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of November 23, 1979 (44 FR 67231), FDA announced that a food additive petition (FAP 0A3481) had been filed by Thomas J. Lipton, Inc., 800 Sylvan Ave., Englewood Cliffs, NJ 07632. The petition proposed that the food additive regulations be amended to provide for the safe use of methylene chloride as a solvent for decaffeinating tea. Thomas J. Lipton, Inc., an operating division of Unilever, the successor to Thomas J. Lipton, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: March 15, 2000.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–7538 Filed 3–27–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99P–4209]

Determination That Hydrocodone Bitartrate and Acetaminophen Tablets USP, 5 Milligrams/325 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that hydrocodone bitartrate and acetaminophen tablets USP, 5 milligrams (mg)/325 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for this drug product.

FOR FURTHER INFORMATION CONTACT: David T. Read, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments) authorizes the approval, under an abbreviated procedure, of duplicate versions of previously approved drug products. Sponsors of ANDA's do not have to repeat the extensive clinical testing necessary to gain approval of a new drug application (NDA). An ANDA sponsor must, with certain exceptions, show that the drug for which approval is sought contains the same active ingredient(s) in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments included what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is commonly referred to as the ''Orange Book.'' Drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)). Also, before an ANDA that refers to a listed drug may be approved, the agency must determine whether the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

Mallinckrodt, Inc., submitted a citizen petition dated September 27, 1999 (Docket No. 99P–4209/CP1), under 21 CFR 10.30(b) and 314.122(a), requesting that the agency determine whether hydrocodone bitartrate and acetaminophen tablets USP, 5 mg/325 mg, were withdrawn from sale for reasons of safety or effectiveness and, if not, to keep the drug in the Orange Book. Hydrocodone bitartrate and acetaminophen tablets USP, 5 mg/325 mg, are the subject of ANDA 40–099 held by UCB Pharma, Inc. ANDA 40–099 was approved on June 8, 1987, but the product was never marketed. FDA has determined, for purposes of §§ 314.161 and 314.162(c), that never marketing an approved drug product is equivalent to withdrawing the drug from sale.

FDA has reviewed its records and, under §§ 314.161 and 314.162(c), has determined that hydrocodone bitartrate and acetaminophen tablets USP, 5 mg/325 mg, were not withdrawn from sale for reasons of safety or effectiveness. FDA will, therefore, continue to list this product in the Orange Book's ''Discontinued Drug Product List,'' which lists, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to hydrocodone bitartrate and acetaminophen tablets USP, 5 mg/325 mg, may be approved by the agency.